United States Senate
WASHINGTON, DC 20510

January 7, 2009

The Honorable Michael O. Leavitt
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Drug safety is an important priority for the American people, one we know that you take seriously. The FDA Amendments Act of 2007 (FDAAA) requires the Department to modernize its post-market surveillance efforts to examine the safety and effectiveness of prescription drugs taken by patients across the nation. This historic new initiative strengthens the FDA's ability to monitor the performance of a product throughout its entire life cycle, thus enhancing the protection and promotion of public health. This initiative is founded on the growing science of adverse event signal detection, data mining and analysis, and will enable researchers to establish the causal factors of safety problems in the populations using these products.

We understand that the "Sentinel Initiative" is one of the Department's efforts to fulfill the statutory requirements of Section 905 of the FDAAA. In connection with the Sentinel Initiative, it has come to our attention that you have commissioned a joint CMS and FDA post-market drug safety assessment project that relies on linking the vast claims data from the Medicare Part D program to other data sources such as Medicare Parts A and B, and Medicaid. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provided the Department with the authority needed to use Medicare drug event data for the purpose of improving public health through research on the utilization, safety, and effectiveness of health care services.

We're encouraged by your efforts to promote a safer medical marketplace for the American people by exercising authority to use data available through Medicare and Medicaid, and we believe that the inter-agency project has significant promise. With that said, we urge you to fully explore the many legal and public policy issues that may be involved in the use of these data sources. We hope that the Department will pursue a public, transparent process in further developing this initiative. In particular, we would request:

1. Staff briefings on the CMS/FDA project plans as soon as possible but not later than January 16, 2009;

2. An open process by which HHS solicits public comment on the development of standards for the public disclosure of the data and the findings of these studies; and

3. A report to us on the issues raised by this letter, and HHS' proposed solutions not later than June 30, 2009. This report should address, at a minimum:

A. Key findings from the CMS/FDA pilot phase of the Sentinel project.

B. A report on the progress by the Department in meeting the FDAAA goal of observing 25 million lives' worth of data by 2010, and 100 million lives' worth of data by 2012. We would like to review a summary of the Department's internal milestones to ensure that they are consistent with the obligations and goals set forward by the Act.

C. A comprehensive report on the issues, concerns and obstacles of making the findings and the underlying data publicly available. There will be many questions and concerns regarding the standards for and permitted research uses of such data being released, especially in a highly competitive pharmaceutical research marketplace. The issues and concerns range from how the data would be accessed and who could access it for what purposes to the amount of resources that may be needed by the Department to handle the volume and type of requests that may arise. Therefore, we would like to be briefed on HHS' analysis of all the issues involved and the comments it received from the public.

D. A detailed description of how the Department would safeguard and protect Medicare beneficiaries' personally identifiable information and any other sensitive matched data.

We are encouraged to see a promising approach being taken to expand the quality and quantity of information available to help ensure the safety and effectiveness of the drugs being prescribed to Americans and their families. We believe that the promise of the Sentinel Initiative warrants additional Congressional oversight and public attention to ensure the effective development of the initiative as envisioned by Congress with the enactment of the FDA Amendments Act of 2007 and as authorized by the Medicare statute.

We look forward to hearing from you to discuss this important work.

Sincerely,